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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
05/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,356	EMBRECHTS ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants have presented arguments over the 35 USC 112, second paragraph rejection. In particular Applicants assert that the term "co-crystal" is well understood in the art and have supplied an article explaining what co-crystals are. The above arguments are appreciated; however, it is pointed out that there is no teaching of what co-crystals of florfenicol are. The specification does not teach what co-crystals of florfenicol are and how one would obtain them.

Applicants argue over the 35 USC 103 rejection over Nagabhushan in view of Kruse. In particular Applicants argue that Nagabhushan does not teach a composition of florfenicol that is free of organic solvents, which is new claim amendment. Applicants point out the aqueous formulations exemplified by Nagabhushan which contain organic solvents. In response to the above arguments, it is noted that every embodiment need not be exemplified. Nagabhushan teaches that florfenicol is reacted with dialkylamine sulfur trifluoride in an inert organic solvent and goes on to define and inert organic solvent as any organic or inorganic solvent in which the florfenicol is mixed in (Col 7, lines 27-67 - Col. 8, lines 1-5). Therefore, Nagabhushan does not limit the solvent to an organic solvent and the rejection is amended due to Applicants amendments and given below.

Oath and Declaration

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be

either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in Germany on 1/30/2006. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what co-crystals of florfenicol are. There is no teaching to define what a co-crystal of florfenicol is.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagabhushan (US Patent 4,235,892) in view of Kruse et al. (US Patent 5,646,151).

Nagabhushan teaches compositions of florfenicol that are formulated for parenteral, oral or topical administration (Col. 9, lines 41-46 and Col. 10, lines 21-24). Injectable solutions or suspensions are taught (Col. 10, lines 28-30). Nagabhushan teaches by examples that injectable solutions contain water, indicating that the composition is aqueous (see Formulation 5). Nagabhushan further teaches aqueous compositions that include micronized florfenicol (Formulation 1). The amounts of florfenicol in the compositions do not exceed 500 mg/ml (see all Formulations). Nagabhushan teaches the addition of sodium carboxymethylcellulose (see Formulation 1). Further, Nagabhushan teaches that florfenicol can be formulated in inorganic solvents (Col. 7, lines 27-67).

Nagabhusahn does not teach the particle size of the florfenicol, the amount of the buffer, a stabilizer, a polyvinylpyrrolidone, a surface-active agent, an antioxidant or antimicrobial.

Kruse et al. teaches parenteral formulations that include sterile suspensions that include aqueous vehicles, antimicrobial agents, buffers, antioxidants (Col. 34, lines 19-21, 31-39). Kruse et al. teaches that suitable suspending and dispersing agents include

sodium carboxymethylcellulose and polyvinylpyrrolidone (Col. 34, lines 39-42). Kruse et al. teaches that formulations that are suitable for injection may be suspended in micronized form (Col. 36, lines 6-7). Kruse et al. teaches stabilizers that include citric acid (meeting the limitation of a stabilizer of claim 14; Col. 34, lines 44-46). Kruse teaches that suitable compounds for the formulation include florfenicol (Col. 42, line 8).

Accordingly, it would be obvious to a person of ordinary skill in the art to combine the teachings of Nagabhusahn which teaches micronized florfenicol suspensions, with the teachings of Kruse et al. which teach formulations that are suspensions that contain ingredients such as buffers, antioxidants, antimicrobials and disintegrating agents such as polyvinylpyrrolidone and sodium carboxymethylcellulose. One would be motivated to include the ingredients taught by Kruse in the formulation of Nagabhusahn in an effort to create a stable formulation that will effectively deliver florfenicol to a patient.

Regarding the claim limitation of the particle size of florfenicol, it is noted that Nagabhusahn teaches micronised florfenicol; therefore, it would be obvious that the particles are small because they are micronised.

Furthermore, it is obvious to vary and/or optimize the amount of buffer, stabilizer, sodium carboxymethylcellulose, polyvinylpyrrolidone, antioxidant, antimicrobial provided in the composition, according to the guidance provided by Nagabhusahn and Kruse, to provide a composition having the desired properties such as the desired concentrations to formulate a composition to deliver florfenicol to a patient. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is noted that the K-value of the polyvinylpyrrolidone is a property of the compound. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

It is noted that if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPTQ2d 1161, 1165 (Fed. Cir. 1999).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1627

Renee Claytor